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RESEARCH ARTICLE

Comparison home care service versus hospital-based care in patients with diabetic foot ulcer: an economic evaluation study

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Abstract

Introduction Providing health care to patients at home could be causing the mortality and readmission rates reduction in addition to satisfaction of both patients and health care providers increase. The aim of this study was to assess the cost-effectiveness of home care service compared to hospital based care in patients with diabetic foot ulcer.

Methods An economic evaluation study and a trial study were simultaneously conducted in Iran. In trial phase, patients with diabetic foot ulcer were randomly assigned to the home care or hospital care. The Cost and Quality of life data were determined as measures of the study. Incremental cost-effectiveness ratio was calculated for comparative purposes. The model consisted of five stages of the disease. The Tree Age Pro 2009 and R software's were used for data analysis.

Results 120 patients were enrolled in our trial; among which 30 patients were in home care service group and 90 patients in hospital based care group. The rate of ulcer size reduction in hospital based care was significant (P value = 0.003) in comparison with home care service. The total cost of the home care and hospital strategies were 1720.4 US$, 3940.3 US$ and the total effectiveness were 0.31 and 0.29, respectively. The incremental cost-effectiveness ratio (ICER) was 117,300 US$ per quality-adjusted life year for home care intervention compared to hospital based care. Based on ICER plane home care treatment will be placed on the southeastern quadrant of the Cost-Effectiveness Plane, and is suggested as a more dominant treatment alternative.

Conclusions Regarding current evidence, home care strategy for patients suffering diabetic foot ulcer enjoys more cost effectiveness compared to hospital care. It is suggested that healthcare policy makers determine the tariff for health care services for disease groups according to the activity based costing approach.

Keywords Economic evaluation · Diabetes · Diabetic foot · Cost effective · Randomized trial

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Introduction

The rapid rise in the incidence of diabetes, a serious lifelong condition, is of alarming concern to health care system. Recent data from the World Health Organization (WHO) estimate that by the year 2025, more than 325 million people worldwide will be diagnosed with diabetes [1].

Diabetic foot ulceration is one of the most common complications of diabetes disease and is notorious for its complexity and healing difficulties [2]. The prevalence of foot ulcers ranges from 4% to 10% among individuals with diabetes mellitus [3]. Diabetic foot ulcers (DFU) frequently become infected and are a major.

limb amputations in. Approximately 56% of DFUs become infected during their life cycle [4], and 20% of these patients with infected foot wounds require radical debridement of soft tissue and bone, resulting in some form of lower extremity amputation. The ensuing large wound deficit often requires prolonged healing time and extended hospital stays with a further risk for reinfection. Furthermore, this lengthened and sometimes interrupted healing process impairs patient mobility; causes substantial lost productivity; diminishes quality of life; imposes tremendous medical, psychosocial and financial impacts and presents a significant management challenge to health care professionals [5]. Then diabetic foot ulcers impose tremendous medical and financial burden on our health care system with conservative cost estimates as high as US$ 45,000 per patient [6]. These estimations, however, do not include the deleterious psychosocial effects on the patient's quality of life because of impaired mobility and substantial loss of productivity [7].

Hospital in the home (HiTH) services may offer one means of reducing admission in the hospital demand that result in facilitating the more efficient use of inpatient beds, providing an alternative to in-hospital admission and enabling patients to be transferred home earlier, thereby increasing inpatient bed availability. In other words, a potential to avoid the significant capital costs associated with building and running large hospitals is possible through the utilization of Hospital in the home services [8]. Ambulatory setting would be a representative for the minimum total cost which invest in a tertiary centres [9]. There is different estimation for economic cost of DFU management in different countries. The result of a comparison between five different countries showed that DFU treatment varied from Int$102 in Tanzania (as the lowest cost) to Int$188,645 in the USA (the highest cost). The prolonged and infected wounds in complicated patients with a number of comorbidities is associated with increasing costs [10].In this regard a systematic review suggested that homecare for diabetic patients suffering DFU not only reduces the cost of hospitalization and re-hospitalization because of DFU, but also increases the patient health outcomes [11].

As an advantage of home care for DFU management, one study indicated that the storage of open-but-unused wound dressings (which inevitably saved at home) compared to newly opened ones did not increase the rate of microbial contamination [12]. However, low-quality evidence is generally available about home care and additional research would be required [11].

Diabetic Foot care in home setting needs a multidisciplinary approach provided by healthcare providers with home-based abilities [13].In addition, there are some important challenges in this area such as lack of enough information about the treatment costs and discriminatory terrif in Iran, and also weakness in delivering home care service [14]. In Iran, we face rising in the number of diabetic patients [15], so it is important that more knowledge is gained about the effectiveness and cost-effectiveness of different strategies such as home care in patients with diabetes. Then we decided to conduct a clinical trial and cost evaluation, using dual-modality measurements to compare the cost-effectiveness of care delivery at hospital vs. home in patients with DFU. We focused on outcomes indicators in two groups of home and hospital care recipients, their quality of life, and the associated direct and indirect costs.

Methods

Setting and participate

We conducted a randomized controlled trial and an economic evaluation study. The interventional study was in form of non-equivalent and patients admitted in the hospital with diagnosis of DFU were recruited in the trial. The participants were randomly assigned into two groups considering the type of services they were receiving whether home care or hospital care. Inclusion criteria was a primary diagnosis of DFU (Wagner stage 2, 3, 4 and Ankle Brachial Index (ABI) >0.5, patient's physician must agree with early discharge to home care service (HCS), possibility to reside in Tehran city for patients in home care group and exclusion criteria were unstable or non-satisfied patients for transfer to the home care intervention.

The economic evaluation study was conducted to compare the outcomes of diabetic foot treatment between the two modalities named hospital base and home care. This study was implemented in a public teaching hospital affiliated to Tehran University of medical sciences (from April 2016 to October 2017).

Sample size

Sample size was calculated according to 80% study power, and also the probability of observation due to chance was 5%. Finally, 120 patients were recruited using a systematic

sampling technique (30 patients in home care services (HCS) and 90 patients hospital-based care (HBC)).

Randomization and blinding

List of patients admitted with DFU in hospital were obtained from bed manager's daily, after examining the inclusion criteria by one of the researchers (MA),who did not interface in data gathering or intervention, the allocation was conducted through the block randomization. In this regard, a numerical list generated by excel software was used. Then, the participants were categorized into four blocks and then 1 and 3 patients randomly entered to HCS and HBC, respectively. Participants were selected and evaluated by the same researcher. Because of the nature of our intervention, we were unable to mask patients but one of the research assistant who was blinded after assignment to interventions was responsible for the final evaluation of all participants based on the study model and outcomes assessment, too.

Health outcome measure

The outcomes included the rate of reduction in ulcer area, rate of amputation, healed, death and infected ulcer, length of stay and quality of life.

Intervention and data collection

An independent data collector team observed all admitted patients with DFU and collected patient's information (including age, sex, medical and clinical data and cost data). HBC received conventional care while HCS receive the home care treatment. After the patients were assigned into the modality of treatment at home, a trained nurse, responsible for home care, explained the purpose and procedure of the study to the patient and his/her family. If patient agreed to continue treatment at home, the home care provider team was introduced to the patient and the hospital discharge process was arranged accordingly. The patient was then discharged and received HBHC for an average 3–4 weeks. However, this period extended for some patients based on physician's clinical judgment. Home care providers were active 24 h a day, 7 days a week and were available to be contacted by patients when need raised. In addition, patients were also able to contact a senior hospital nurse, at every hour of the day. Also, patients under the HBHC had full access to the hospital services led by the senior HBHC nurse. The treatment of patients with diabetic foot ulcer was performed according to the clinical guideline approved by the Ministry of Health in Iran. The home visit team consisted of a general practitioner (GP) and 3 nurses. Average duration of each visit was 30–40 min. Following the initial home visit, additional home visits were conducted at least once a week. One ratter person was sent as an observer to the patient's home once a week to monitor the process of home care services and to interview patients. In addition, further information on study outcomes was obtained at the end of intervention for the sake of study.

Statistical methods

The continuous variables were tested for normality situation, and the Mann-Whitney U test was used for calculating the average differences, the T student for continuous variables, and the Chi square for categorical variables. In order to express the differences between the two groups in terms of healing and amputation rates, a multivariate binary logistic regression was performed at a significant level of %5- to control the effect of confounding variables such as age, duration of disease, smoking, family history, location of ulcers, and antibiotic use. All analyses were performed based on intention to treat (ITT) analysis. A summary of the statistical findings of the study population at the baseline (i.e., age, sex, duration and type of diabetes, employment situation) are presented for control and intervention groups using descriptive tests (i.e., mean and median).

Decision analysis model

Based on the gained clinical evidence in trial phase and compiled cost data, the decision tree model was designed for cost-effectiveness analysis in which two modalities named of HBS, HCS. In this model, 30 patients were included in the HCS and 90 patients were enrolled in HBS. Our model consists of 5 states; healed, gangrened, amputation, infectious, and death that was extracted from other studies and was approved by a focus group discussion Therefore, in terms of reliability and reliability, it is at the appropriate level. Meanwhile the mentioned stages considered based on patient situation after 6 months (See model in Fig. 1).

Model inputs

Cost data, quality-adjusted life year (QALY) and the possibility of 5 stages in each modalities. (See Fig. 1).

Effectiveness

Health outcome is specified in terms of QALY. It be considered as a measurement that combines the number of lived years with the quality of those years. We obtained utility scores using EQ-5D questionnaires administered via face-to-face interviews in the base-time and by phone in follow-up period at 6 months after discharge from home care and hospital care (±2 weeks). The missing data was specified in follow-up period, then we imputed missing data by R software based on Edwards' study; we assumed the similarity in utility score

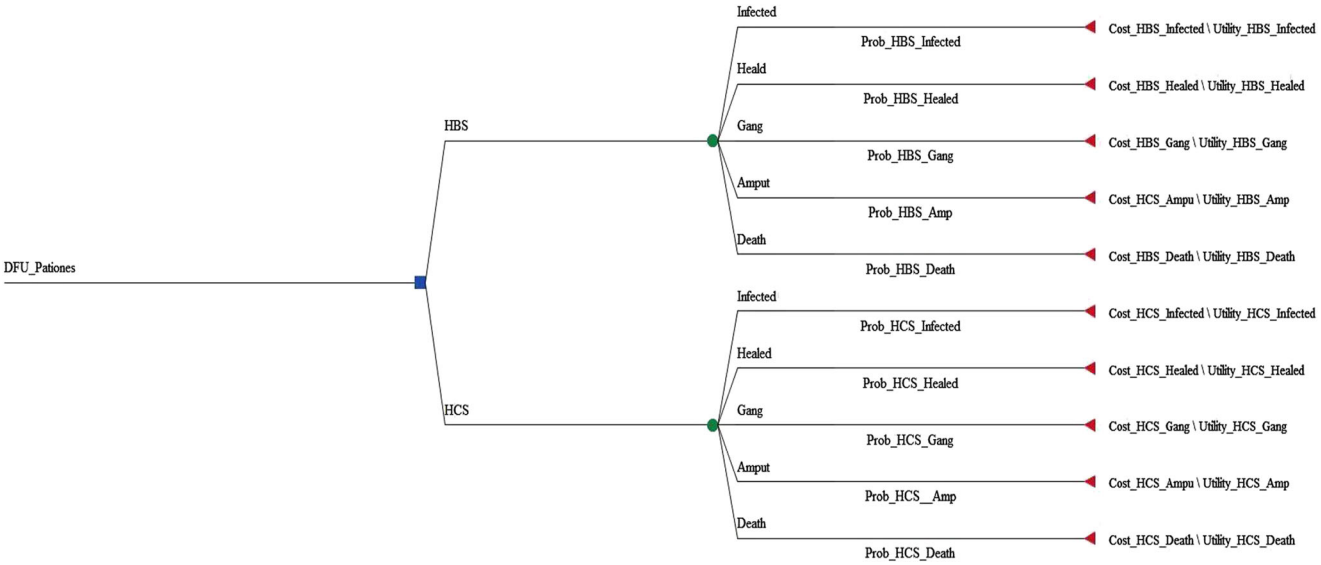

Fig. 1 Decision tree modeling for the cost- effectiveness of patient with DFU

across the two study groups in the base-time as well as using the straight line transitions between baseline and follow up [16, 17]. After that we multiplied the follow-up utility scores data in the study period (6 months equivalent 0.5 year). Meanwhile, any deaths were registered as zero in the utility for the assessment period.

Resource use measurements

The resource use measurements included both direct (medical, non-medical) and indirect costs. Cost of data was collected from 120 included patients treated in hospital and home care modalities retrospectively based on study group from social perspective. Cost information was obtained from various sources including hospital information system, accounting unit, patients' records, and through completing the questionnaire by asking the patient or his/her family. The resources were categorized into medical cost including in-patient and out-patient services (i.e., hospitalization cost, out-patient surgery, physicians' visits, nurses' visits, physiotherapists' and occupational therapists' visits, X-ray and lab examinations and relevant pharmaceuticals for Diabetic patients) and non-medical costs (e.g., travel expenses, accommodation) and indirect costs (loss of production).

Table 1 Demographic data of the subjects ($N = 120$)

	HCS		HBC	
Item	N	%	N	%
sex (male)	22	73	58	64
age (Ave, SD)	61.7 (11.1)	–	58.5 (10.9)	–
Los (days, AVE)	20	–	19.9	–
Employment	10	34	23	25
type of diabetes	20	66	74	82
type 1	2	5	4	4
type 2	28	95	86	95
length of illness				
5>	3	10	9	10
6–10	3	10	24	26
< 11	24	80	57	63

HCS, home care services; *HBC*, hospital-Based care

Table 2 Characteristic of DF ulcers

Variables		Hospital care ($N = 90$)	Home care ($N = 30$)
Type of wound (N, %)	Ischemic	15 (15%)	5 (16%)
	Nouroischemic	19 (19%)	10 (30%)
	Nouropathy	59 (60%)	14 (46%)
	Vein ulcer	5 (5%)	2 (6%)
Severity of ulcer (N, %)	Wagner 2	46 (51%)	8 (26%)
	Wagner 3	28 (31%)	19 (63%)
	Wagner 4	16 (17%)	3 (1%)
Sepsis (N, %)	Mild	19	3
	Moderate	32	6
	Sever	19	3
Initial wound size ulcer Cm2 (N, %)	Total	3.46 (2.34)	3. 24 (1.89)
	≤1 cm2	21 (23%)	5(16%)
	1–5 cm2	50 (55%)	17 (56%)
	>5 cm2	19 (21)	8(26)

*Significant

Aforementioned costs for each patient were calculated. Afterwards the costs of patients according to the model classification were accumulated. To calculate the cost of each arm of the decision tree model, the average cost per patient was considered. In our model, costs were evaluated based on time study for 6 months. Costs were calculated based on US dollar (Cost is calculated on the basis of US dollars in 2017; each dollar equivalent 42,000 Rail).

By comparing the costs and effectiveness of two modalities, we calculated the incremental cost effectiveness (ICER), the ratio of the ICER (R) was calculated from the below formula:

$$R = \frac{\overline{C}_T - \overline{C}_C}{\overline{U}_T - \overline{U}_C} = \frac{\Delta\overline{C}}{\Delta\overline{U}}$$

Where CC and UC are average costs and effectiveness in the control group (HBC), CT, UT represents average cost and effectiveness in the treatment group (HCS).This ratio projects a point estimate of the average costs per QALY. Tree Age Pro 2009 software was used for data analysis.

Sensitivity analysis

Tornado diagrams are used for deterministic sensitivity analysis to investigate the effects of utility and cost and probability data and also to determine the effect of the plausible changes of these parameters on the stability and generalizability of our model.

The sensitivity analysis was performed for the parameters with the greatest impact on the cost-effectiveness analysis. we considered 20% changes in the parameters (utility and cost and probability data) that was obtained from other studies [18]. This study didn't need time horizon for QALY and costing discounting.

Ethical consideration

The study protocol was approved by the Ethics Committee of Tehran University of Medical Sciences IR.TUMS.EMRI.REC.1395.0081 and was then registered at the Iranian Center for Clinical Trials IRCT2017080935600N1.

Results

Patient characteristics

There was no significant difference between the HBC and HCS groups in the demographic characteristics. These characteristics of patients are shown in Table 1. The ages of two groups were not significantly different ($p = 0.36$). The majority of subjects were unemployed and above 50 years of age, and belonged to middle socioeconomic level. Ninety percent of participants had type 2 diabetes and suffered from DFU more than 5 years.

Table 3 Outcome indicator in participants included home care VS hospital care

	Control group (n = 90)	Intervention group (n = 30)	P
reduction in ulcer area (mm2) (mean, SD)	(−65.05,361.5)	(−256. 445.2)	<0.001
Rate of healed N (%)	28 (31%)	20 (66%)	0.01
Rate of amputation N (%)	16 (17%)	0 (0)	0.01
Rate of Death by 6 months N (%)	15 (16%)	6 (20%)	0.6
Rate of Unhealed N (%)	30 (33%)	4 (13%)	0.03
Length of stay (days) Mean (SD)	20.3 (14.5)	21 (1.01)	0.7

Diabetic foot ulcer

The most common type of ulcer was neuropathy in both groups (Table 2). The wound were unilateral in 64% and bilateral in 5% of cases. Also, most of ulcers had moderate infection in both groups. The Paired t-test showed that the size reduction in HBC was significant (P value = 0.003) in comparison with HCS. 38% of patients experienced complete healing after 4 weeks. 28% of patients did not show wound healing in 3 weeks (Wagner's incremental changes, infections, gangrene, and amputation). The ratio of the healed patients in the intervention group was significantly higher than the controls, and none of the patients underwent amputation in HCS group, 17% of controls underwent amputation. Death was reported in 17% of patients within 6 months after discharge (Table 3).

Economic evaluation

Table 4 shows the costs of two care modalities separately. The average cost for the HCS and HBC were 1545 $ and 3891.4 $ (including medical, nonmedical and indirect costs), respectively. To calculate the cost of each arm of the decision tree

Table 4 Cost-data (costs in US dollars)

	Control group Ave cost ($)	Intervention group Ave cost ($)
hospitalization	2771	1057.63
Medications	30.6	26.90
Par-clinic	88.7	20.9
Visits	440.6	603.78
Total Medical cost	3001	1119.73
non-medical costs	413.4	264.2
indirect costs	525.9	336.5
Total cost	3940.3	1720.4

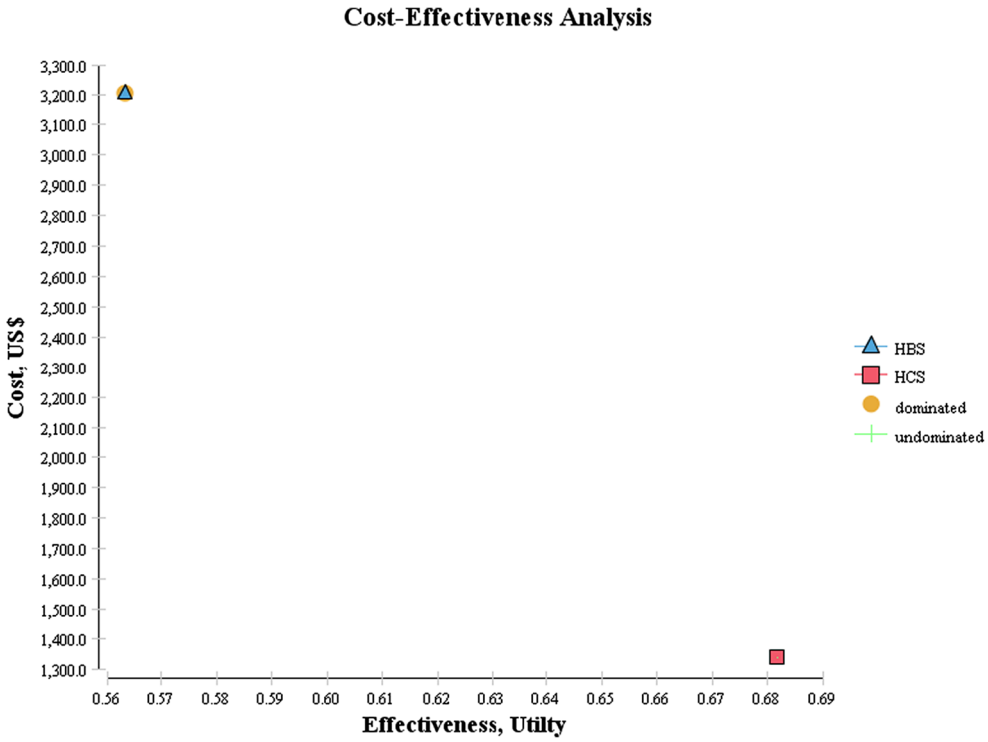

Fig. 2 Cost-effectiveness ratios on the cost- effectiveness plane

model, the cost per patients in each arm accumulated, after that averaged and included in study model.

Total effectiveness in the HCS group were more than HBC group but this differences were not significant based on the results of the statistical tests ($p > 0.4$).At baseline, the utility weight was 0.72 and 0.69 for HBC and HCS groups, respectively. After 6 mounts follow-up period, the HCS (0.63) and HBC (0.58) had a decrease in the utility both of the groups. QALY in the HCS and HBC groups were 0.31 and 0.29, respectively (Mean diff −0.03, 95% CI -0.12 to 0.05).

Analysis of the cost and effectiveness data resulted in the decision tree for two groups (HCS and HBC) showed that cost-effectiveness (C/E) ratio was 1545 USD per QALY for home care strategy and 3891 dollars per QALY for hospital care strategy. Then, the superior arm for care of patients with diabetic foot ulcer is home care intervention because these patients gain more QALY with fewer costs. Figure 2 shows the cost-effectiveness analysis in which the home care intervention is located at the dominated region (Tables 5 and 6).Tornado diagram shown in Fig. 3 demonstrates that the parameters had the greatest impact on ICER. But according to the results of the One-way sensitivity analysis, the result of HBC was not sensitive to changes in these variables.

Discussion

Based on the results of economic evaluation, HCS in patients with DFU is more cost effective than HBC. The actual cost saving was estimated based on costs per patient.

The results of a study by Haggerty,similar to the present study, reported a reduction in the use of hospital resources and health care costs following home care [19]. Some studies also found a decrease in the use of hospital resources during home care services [20]. The reduction in patient costs in the Cumming study also points out that this cost reduction has been linked to the reduction in occupancy rates for hospital beds [21], Therefore, home care for some disease groups seems to be cost-effective due their probable application to use hospital resources for other patients. But HCS requires a hardware and soft infrastructure that includes prediction equipment for patients who can't afford buying or rent equipment (oxygen and suction, etc.), as well as the need for protocols for diseases that indicate the transition to home care.

The study of Oldridgeet al examined the costs and quality of life of patients with acute heart failure during the 8-week in 2 groups who received home care and hospital care. Following the treatment, they reported that ICER and QALY

Table 5 The incremental cost-effectiveness ratio (costs in US dollars)

Intervention	Effectiveness	Incremental effectiveness	Cost	Incremental cost	ICER
Home care	0.31	–	1545	–	–
Hospital care	0.29	0.02	3891	−2346	−117,300

Table 6 Cost and effectiveness comparison based on the model

State	Control group		Intervention group	
	Ave cost ($)	QALY	Ave cost ($)	QALY
Infected	3404.59	0.28	1903.71	0.30
Gangrene	1691.04	0.28	–	–
Amputation	7377.31	0.29	–	–
Healed	2508.85	0.28	1628.34	0.28
Death	4473.45	0	1105.62	0

were $ 480 and $ 0.052 and ICER was $ 9200 per QALY [22]. The finding of the so called study is similar to the results of this study.

To the best of our knowledge, the study did not address the cost effectiveness of treating diabetic foot ulcers at home and in the hospital. Therefore, there was hardly any clinical and costly evidence to compare treatment in this disease.

Limited studies were conducted on the safety of home-based treatment that has adequate strength and the assessment of the risks of adverse events. Because some studies pinpointed that limiting the spread of this type of treatment is limited by the inability to carry out some homeopathic treatments at home. Therefore, there is a significant gap in the published studies on the safety of home care as well as some disease groups such as diabetic foot ulcers.

Cost analysis in HCS isn't under the coverage of health insurance system as well as different cost-accounting studies still require trial studies with acceptable sample sizes. The type of treatment at home and the difference between home care and the hospital are affected by actual and not necessarily patient billing. And the difference between studies comes from whether only direct costs or indirect costs are taken into account. Stevens' study reported no efficiently, in discussing financial aspects, spending does not arise from the perspective of the community, so their interpretation should be cautious [23].

Limitation

Despite the long duration of the study, the number of patients receiving HCS was less than HBC because the majority of patients did not have possibility of residency in Tehran city as a one of the inclusion criteria and consequently, they didn't enter into the study.

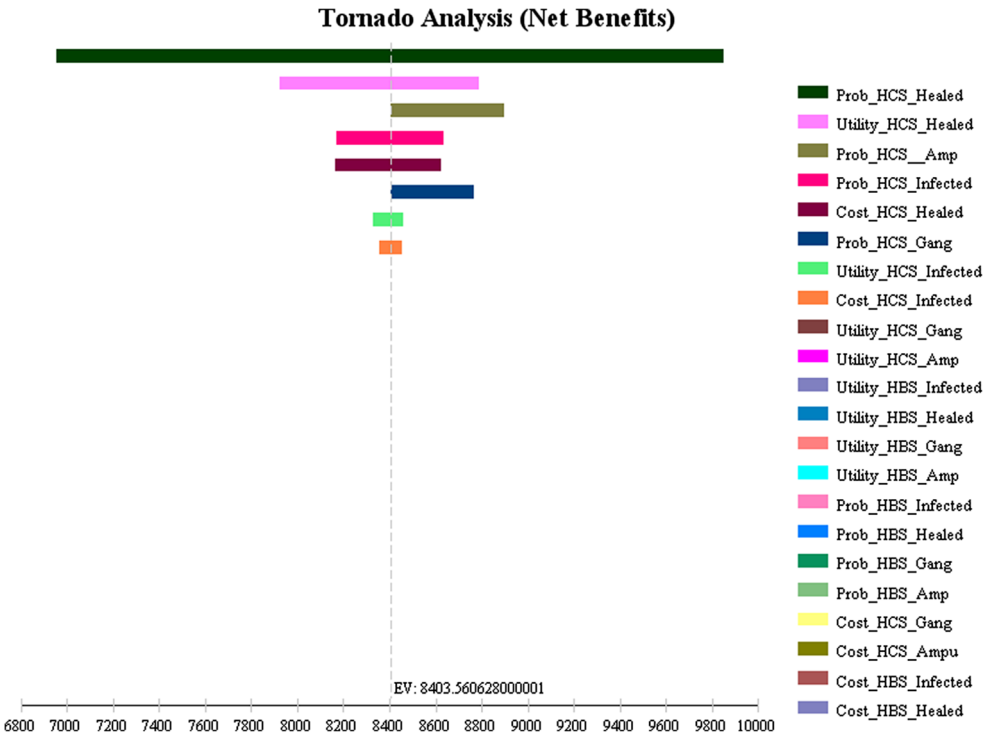

Fig. 3 Tornado diagram for sensitivity analysis

Conclusion

The results of this study showed that HCS delivery for patients with DFU is more cost effectiveness than hospital care. Considering that home care services in Iran doesn't have possibility to be provided for all patients admitted to the hospital and isn't covered by the health insurance, the implementation of home care services may be challenging. Therefore, it is suggested that healthcare policy makers should determine the tariff for health care services for disease groups according to the ABC approach and different tariff's should be applied to home care based on severity, type of disease, and equipment in patients.

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Authors' contributions ZN: Designing the methodology, reviewing of the literatures, and writing the original article.

MA, MM: Performed randomization and supervision on HBS provider performance

ZN, ZG: Cleaning and analyzing data (data imputed and economic evaluation)

MJ: Doing requirement research at hospital

MS, MA: Editing the article

All authors read and approved the final manuscript.

Compliance with ethical standards

Conflict of interest The authors declare that there is no conflict of interest regarding the publication of this article.

Ethics issues The study protocol was approved by the Ethics Committee of Tehran University of Medical Sciences IR.TUMS.EMRI.REC.1395.0081 and was then registered at the Iranian Center for Clinical Trials IRCT2017080935600N1.

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